United States Environmental Protection Agency

National Ambient Air Quality Standards (NAAQS):
SO_2 (Primary) REA Plans

Presentation for the CASAC

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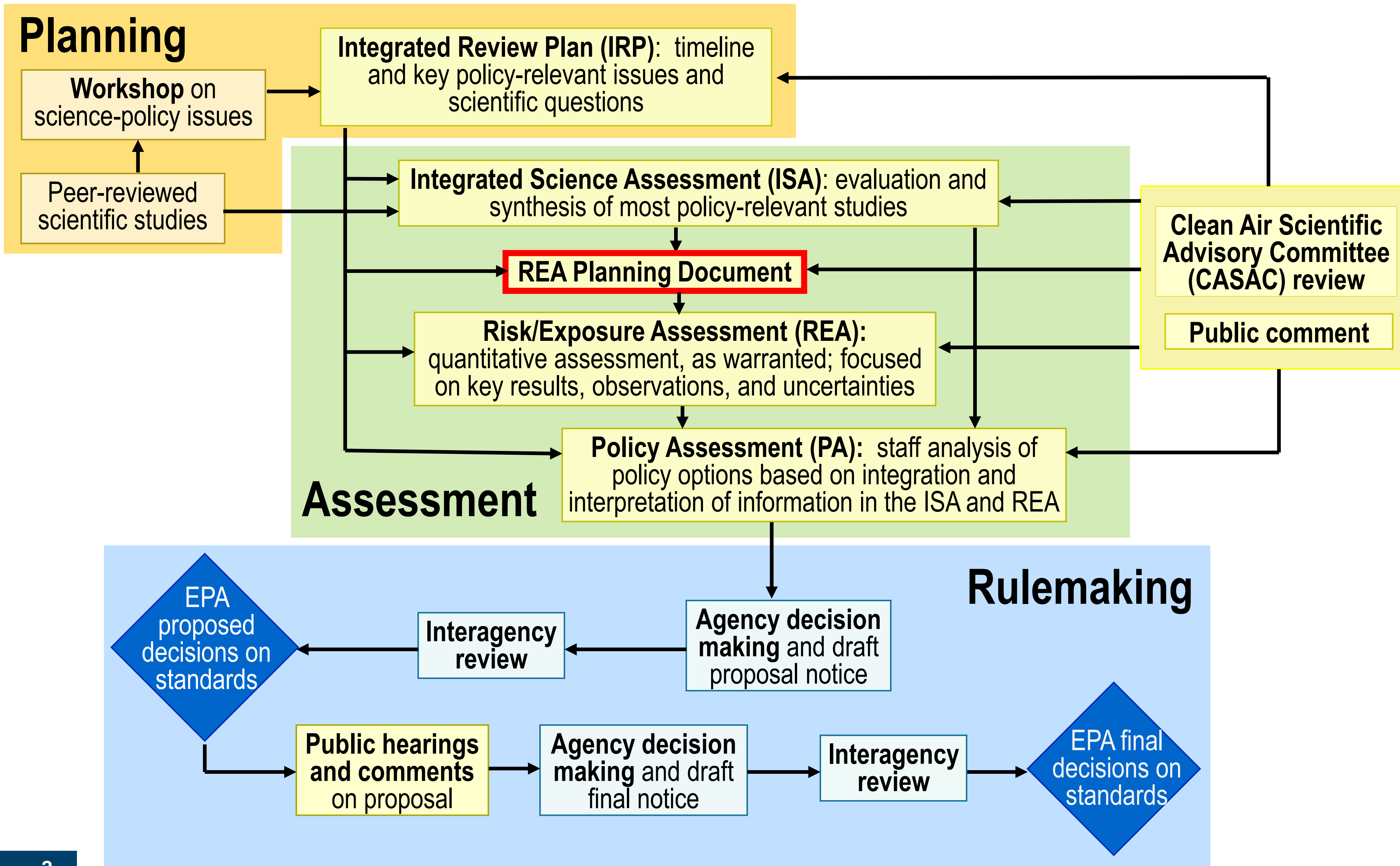
NAAQS Review Process



SO_2 REA Planning Document

- Chapter 1: Introduction, Background, and Conceptual Model
- Chapter 2: Overview of Previous Assessment
- Chapter 3: Consideration of Newly Available Information
  - Key Considerations
  - Health Effects Information
  - Ambient Air Concentrations
  - Exposure Estimates
- **Chapter 4: Plan for Current Health Risk and Exposure Assessment**
  - **Population-based Exposure Assessment**
  - **Health Risk Characterization**
  - **Assessment of Variability and Characterization of Uncertainty**

Key Health Effects Evidence (confirmed in current review)

- Causal relationship for respiratory effects and short-term (5-10 minute) SO_2 exposures based primarily on controlled human exposure study data
  - Individuals with asthma
  - After exercise (i.e., while at elevated ventilation)
  - Lung function decrements

- Thus, an exposure-based approach that accounts for exertion levels is needed to best characterize potential health risk

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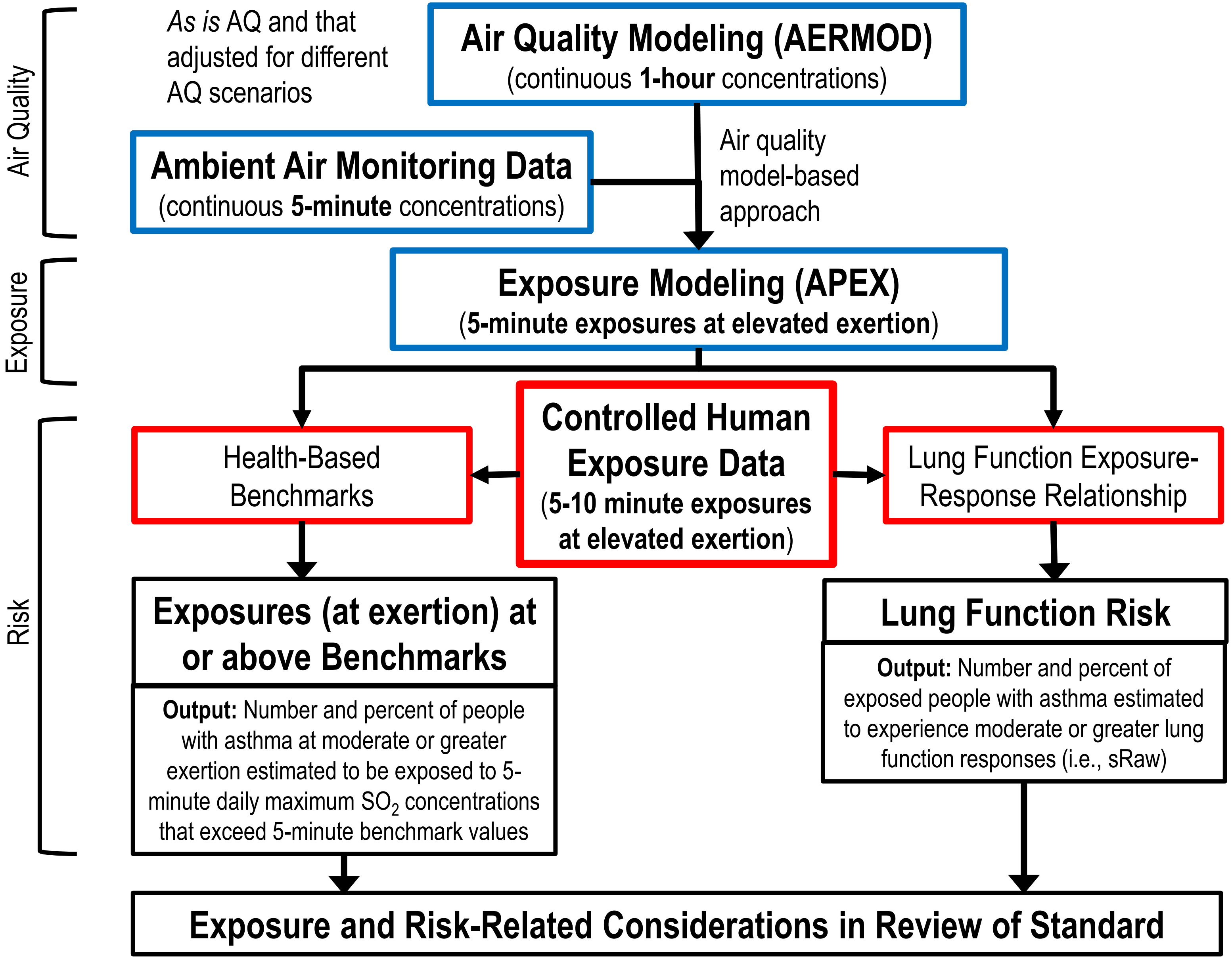
Overview of REA Planned for this Review



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Newly Available Information to Support REA Development for this Review

- Ambient monitoring data
  - The currently available air quality data, particularly 5-minute SO_2 concentrations, is vastly expanded from previous review
  - New data will provide an improved, local estimate of 5-minute SO_2 concentrations
- AERMOD air quality modeling
  - Several model improvements (new model options, processing tools, new inputs) will increase confidence in predicted hourly SO_2 concentrations
- APEX exposure modeling
  - Several model improvements (new model options, algorithms, new inputs) will provide improved estimates of 5-minute SO_2 exposures
- E-R function for estimating risks
  - Updated E-R function using additional controlled human exposure study data will provide improved estimates of the portion of the population expected to experience lung function decrements

Summary of Plans for REA

- An exposure-model based risk assessment will be conducted for 2-3 study areas
  - Fine scale spatial and temporal SO_2 air quality surfaces will be generated by combining AERMOD and local ambient monitor concentrations
  - The complete time-series of 5-minute SO_2 exposures for all simulated individuals will be directly linked to instances of moderate or greater exertion using APEX
  - Risk outputs will include both comparisons of exposures to benchmarks and population risk of “moderate” or greater SO_2-related lung function decrements

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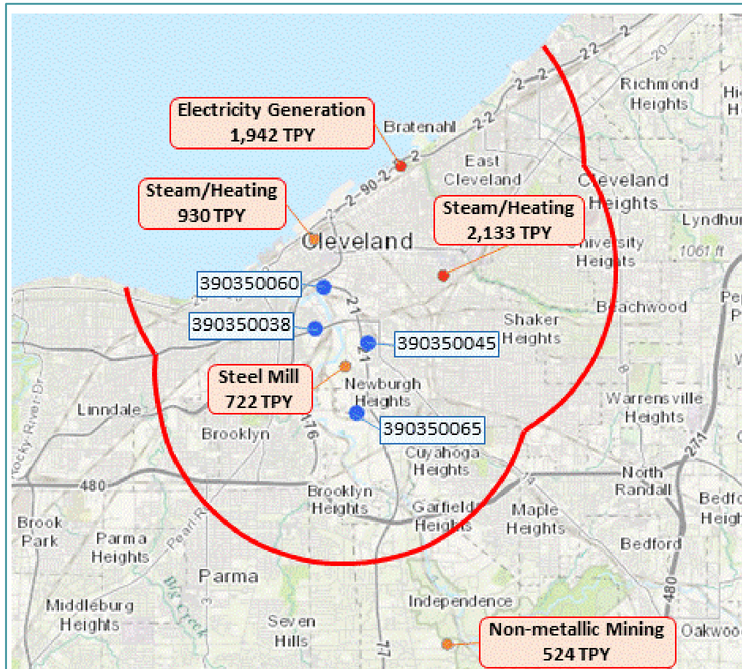
Key Analytical Features of REA: Study Area Selection & Modeling Domain

- Selecting Study Areas
  - Assess monitor data completeness (75%)
  - Evaluate SO_2 design values (65 - 85 ppb)
  - Population (>100,000) within 10 km of monitor
  - Areas having at least one 5-minute monitor
  - Source configuration (emissions > 100 tons per year within 10 km of monitor)
- Defining Study Area Domain
  - All receptors within 10 km radius of emission sources
- Potential Study Areas
  - Brown County, WI
  - Cuyahoga County, OH (Figure 4-3)
  - Hillsborough County, FL
  - Marion County, IN



Map indicating SO_2 emission sources > 100 tons per year (red-orange dots), ambient monitors (blue dots), and approximate dimensions of potential study area (red arcs extending 10 km from emission sources), in Cuyahoga County, OH. Modified from Figure 4-3, REA PD.

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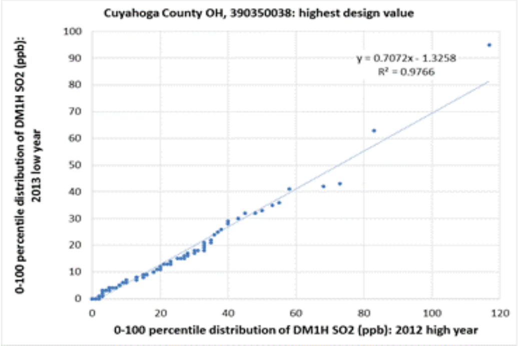
Key Analytical Features of REA: Temporal/Spatial Representation of Air Quality Surface

- Adjusting ambient concentrations to represent air quality scenarios
  - Proportional approach to be used (e.g., supported by Figure 4-6)

- Estimating missing ambient monitor concentrations
  - methods for hourly, 5-minute maximums, or 5-minute continuous (e.g. linear ramp, Equation 4-2)

- Combining fine spatial scale of AERMOD predicted 1-hour concentrations with the fine temporal scale of ambient monitor 5-minute concentrations
  - (e.g., Equation 4-4)



Comparison of low and high concentration years using recent data (2011-2015) for daily maximum 1-hour SO_2 concentrations in ambient air in Cuyahoga County, OH. From Figure 4-6, REA PD.

$$C_i = \frac{(i-1)[(12 \times H) - C_{12}]}{55}$$

Equation 4-2, REA PD

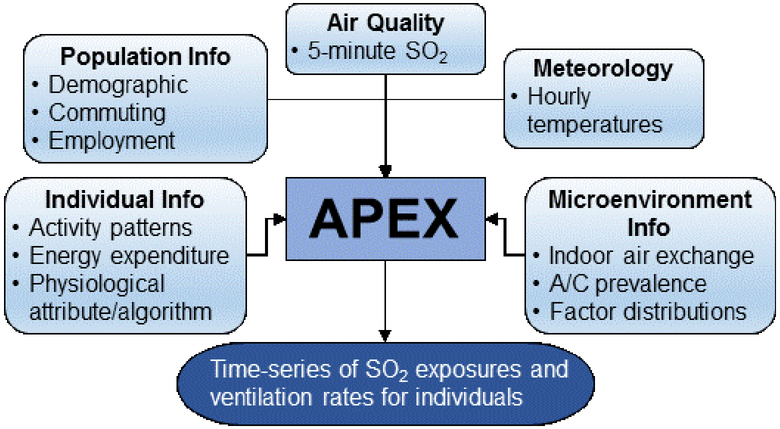
$$Y_{shi} = \frac{Y_{sh}}{\frac{1}{12}\sum_{i=1}^{12} X_{hi}} X_{hi}$$

Equation 4-4, REA PD

Key Analytical Features of REA:

Modeling Exposed Individuals at Elevated Exertion Levels

- Using APEX to estimate the complete time-series of 5-minute SO_2 exposures and ventilation rates for all simulated individuals



- Representing population study group
  - Estimated census tract level asthma prevalence (e.g., Table 4-1)

Table 4-1. Estimated asthma prevalence for children and adults in four potential study areas.

Study Area (# tracts)	Study group	Asthma Prevalence (in percent of population) mean	minimum	maximum
Brown Co., WI (54)	child	11.1%	9.8%	13.6%
	adult	7.9%	6.4%	9.3%
Cuyahoga Co., OH (443)	child	11.9%	9.4%	16.0%
	adult	8.4%	7.0%	12.4%
Hillsborough Co., FL (316)	child	10.5%	8.7%	13.1%
	adult	6.8%	6.0%	8.9%
Marion Co., IN (224)	child	12.0%	9.0%	15.0%
	adult	8.4%	7.2%	10.4%

Based on combining information from CDC NHIS asthma prevalence and US census income/poverty ratios. Prevalence statistics in this table are based on tract-level summaries within each county that were generated by aggregating age (or age group), and sex specific prevalence estimates, and weighted by each age/sex specific population. The mean is average of all tracts, the minimum is the lowest prevalence in a tract, the maximum is the highest prevalence in a tract, within each the county.

From Table 4-1, REA PD

- Identifying when exposures occur while an individual is at moderate or greater exertion

Equivalent Ventilation Rate (EVR)
EVR = ventilation rate/body surface area
or
21 L/min-m²

Key Analytical Features of REA:
Exposure Benchmark Levels

- 5-minute benchmark levels
  - 100, 200, 300, and 400 ppb
  - Based on data from controlled human exposure studies (Table 5-2, ISA)
    - Individual subject data for two additional studies are available for this REA, though conclusions regarding benchmark levels remains the same as last review

- APEX Risk Calculation
  - Estimated number (and percent) people with asthma (including children) having 5-minute exposures at or above benchmarks occurring while at moderate or greater exertion

SO_2 Conc (ppm)	Exposure Duration (min)	N	Ventilation (L/min)	sRaw / FEV_1	Cumulative Percentage of Responders (Number of Subjects)[a]: =100% ↑ sRaw / =15% ↓ FEV_1	=200% ↑ / =20% ↓	=300% ↑ / =30% ↓	Study	Respiratory Symptoms: Supporting Studies
0.2	5	23	~48	sRaw	9% (2)[b]	0	0	Linn et al. (1983b)	Limited evidence of SO_2-induced increases in respiratory symptoms in some people with asthma: (Linn et al. (1990); Linn et al. (1988); Linn et al. (1987); Schachter et al. (1984); Linn et al. (1983b))
	10	40	~40	sRaw	7.5% (3)[c]	2.5% (1)[c]	0[c]	Linn et al. (1987)[c]	
	10	40	~40	FEV_1	9% (3.5)[c]	2.5% (1)[c]	1% (0.5)[c]	Linn et al. (1987)[c]	
0.25	5	19	~50-60	sRaw	32% (6)	16% (3)	0	Bethel et al. (1985)	
	5	9	~80-90	sRaw	22% (2)	0	0	Bethel et al. (1985)	
	10	28	~40	sRaw	4% (1)	0	0	Roger et al. (1985)	
0.3	10	20	~50	sRaw	10% (2)	5% (1)	5% (1)	Linn et al. (1988)[d]	
	10	21	~50	sRaw	33% (7)	10% (2)	0	Linn et al. (1990)[d]	
	10	20	~50	FEV_1	15% (3)	0	0	Linn et al. (1988)	
	10	21	~50	FEV_1	24% (5)	14% (3)	10% (2)	Linn et al. (1990)	
0.4	5	23	~48	sRaw	13% (3)	4% (1)	0	Linn et al. (1983b)	Stronger evidence with some statistically significant increases in respiratory symptoms: Balmes et al. (1987)[f], Gong et al. (1995) (Linn et al. (1987); Linn et al. (1983b)) Roger et al. (1985)
	10	40	~40	sRaw	24% (9.5)[c]	9% (3.5)[c]	4% (1.5)[c]	Linn et al. (1987)[c]	
	10	40	~40	FEV_1	27.5% (11)[c]	17.5% (7)[c]	10% (4)[c]	Linn et al. (1987)[c]	

From Table 5-2, ISA

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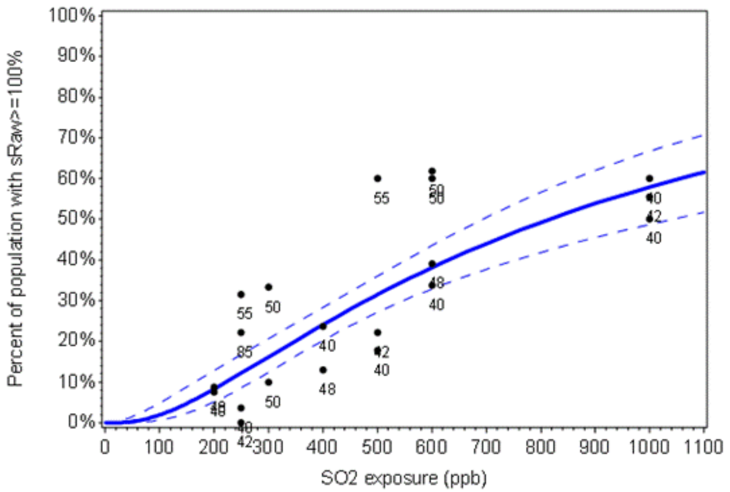
Key Analytical Features of REA:

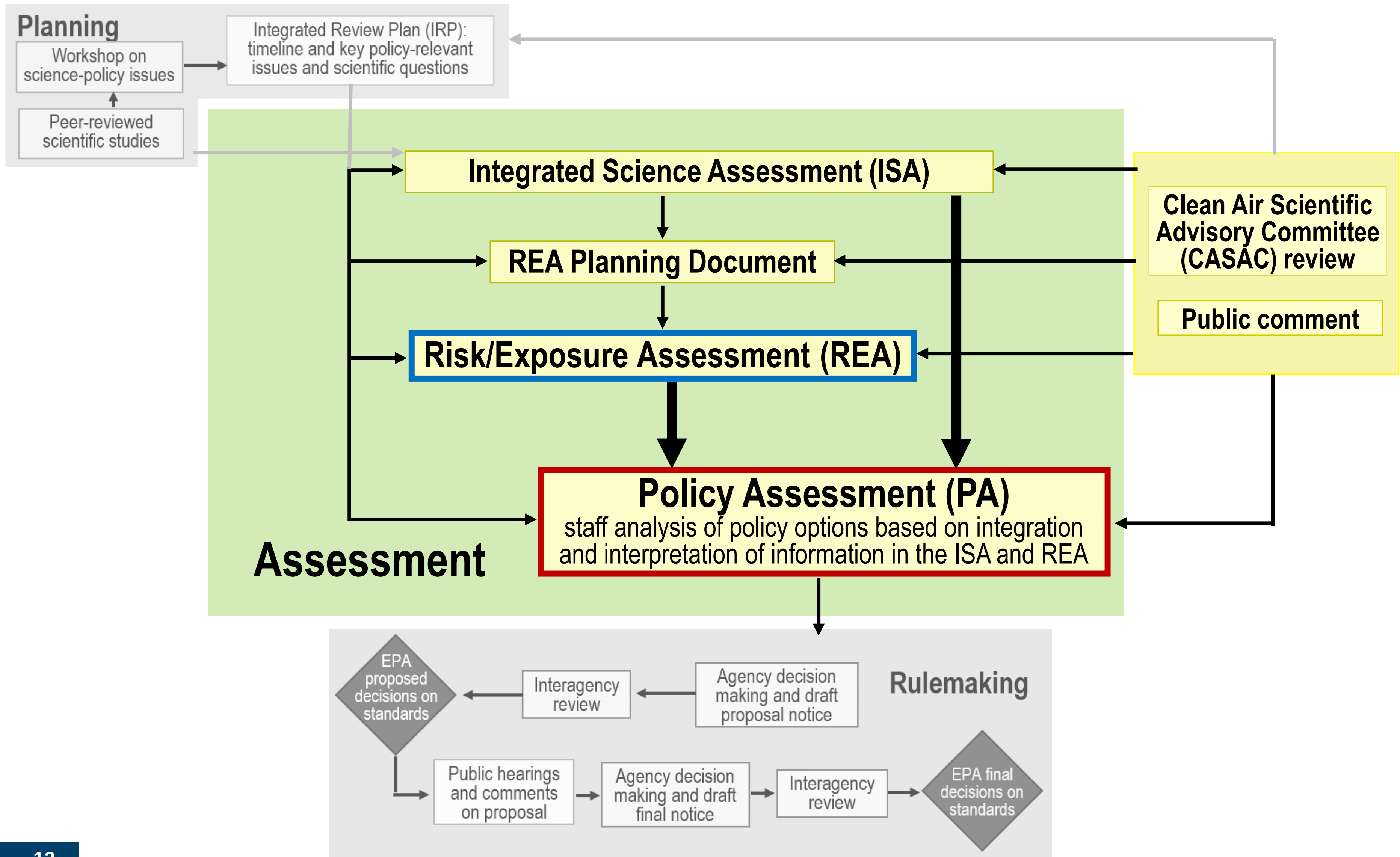
Lung Function Risk Assessment

- Updated exposure response (E-R) functions derived using controlled human exposure study data
  - Risk indicator: Increases in specific airway resistance (sRaw ≥ 100%, ≥ 200%)
  - Individual subject data for two additional studies not used in previous REA
    - Number of study subjects used to develop E-R function increases from 334 to 484 (45%)
  - Link function with fine-scale exposure bins (i.e., 10-50 ppb) for study population
  - Evaluate estimated risk at all exposure levels
- APEX Risk Calculation
  - Estimated number (and percent) people with asthma (including children) expected to experience lung function decrements (e.g., Δ sRaw ≥ 100%)



Percent of individuals experiencing changes in sRaw ≥ 100% using controlled human exposure study data (Table 4-6) fit using a probit regression (solid line). Annotated with the number of study subjects from each study, dashed line indicates a 5th and 95th percentile prediction interval for the mean. From Figure 4-7, REA PD.

Next Steps in the Review Process



Schedule for Current Review of Primary SO_2 NAAQS

Stage of Review	Major Milestone	Target Date
Integrated Review Plan (IRP)	Final IRP	October 2014
Integrated Science Assessment (ISA)	1st draft ISA	November 2015
	CASAC review of the 1st draft ISA	January 27-28, 2016
	2nd draft ISA	December 2016
	CASAC review of the 2nd draft ISA	**March 20-21, 2017**
	Final ISA	December 2017 *
Risk/Exposure Assessment (REA)	REA Planning Document	February 16, 2017
	CASAC review of REA Planning Document	**March 20-21, 2017**
	Draft REA	Summer 2017
	CASAC review of draft REA	Fall 2017
	Final REA	Spring 2018
Policy Assessment (PA)	Draft PA	Summer 2017
	CASAC review of draft PA	Fall 2017
	Final PA	Spring 2018
Rulemaking	Proposed Rule (PR)	May 25, 2018 *
	Final Rule (FR)	January 28, 2019 *

*We anticipate that these actions will be subject to court-ordered deadlines, as EPA is currently being sued for missing the statutory deadlines for this review.

Appendix

Health Risk: Other Endpoints (based on epidemiological studies)

- Previous Review
  - An epidemiological-based risk assessment was not conducted
    - Only “causal” or “likely causal” determination is for short-term exposures and respiratory morbidity
      - In those U.S. cities where epidemiological studies had been conducted, many of the SO_2 effect estimates were positive, but not statistically significant in single pollutant models
      - Multipollutant models including PM_{10} showed a weakening of effect in approximately 50% of the studies
- New information
  - ISA: No change to “causal” or “likely causal” determinations
  - For short-term exposures and respiratory morbidity: While four new U.S. studies identified,, they have uncertainties similar to previous review among additional uncertainties
    - Study design not specific to SO_2 (often $PM_{2.5}$ and O_3 were highly emphasized), thus key SO_2-specific exposure conditions (e.g., local gradients) were not considered
    - Potential co-pollutant confounding remains an issue
  - No long-term causality determinations of “causal” or “likely to be causal”
- Current Review
  - Currently available evidence does not support conducting a quantitative epidemiology-based risk assessment

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History of Primary SO_2 NAAQS

- **1971**: Established annual SO_2 standard at a level of 0.03 ppm and 24-hour SO_2 standard of 0.14 ppm (not to be exceeded more than once per year)
- **1996**: Retained annual and 24-hour standard
- **2010**: Annual and 24-hour standards revoked; Established a 1-hour standard with a level of 75 ppb (99th percentile, averaged over 3 years)
  - Controlled human exposure studies provided the most direct evidence of respiratory effects, particularly 5-10 minute SO_2 exposures ≥ 200 ppb
  - Epidemiologic studies reported statistically significant SO_2 effects in multipollutant models with PM for respiratory-related hospital admissions and emergency department visits
  - Quantitative exposure/risk analyses provided supporting information, including exposure-based assessment for individuals with asthma at elevated ventilation that included benchmark comparisons and estimated lung function decrements in two study areas (St. Louis and Greene County MO)